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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	K0208.014	5214

23723            7590            12/30/2002

Patterson Belknap Webb & Tyler, LLP  
Attention: I.P. Docketing  
1133 Avenue of the Americas  
New York, NY 10036

[REDACTED] EXAMINER

SAYOC, EMMANUEL

ART UNIT	PAPER NUMBER
3746	

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/720,762	YANASE ET AL.
	<b>Examiner</b> Emmanuel Sayoc	<b>Art Unit</b> 3746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 18 November 2002.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-8 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 28 December 2000 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
     1.) Certified copies of the priority documents have been received.  
     2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first diameter" and "second diameter" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The diameters may be in the current figures, but the specification does not specify which diameter is the first and which diameter is the second.

***Claim Objections***

2. Claim 5 objected to under 37 CFR 1.75(c) as being in improper form because it is dependent upon multiple dependent claim 4. See MPEP § 608.01(n). Accordingly, the claim 5 has not been further treated on the merits.

3. Claims 4 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims to not provide any physical structural limitation on the claimed apparatus.

***Claim Rejections - 35 USC § 112***

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, line 1 the reference to "diameter" is ambiguous as the gasket contains several diameters.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136).

With respect to claim 1, and 6-8 in Figure 6, Trull et al. discloses a syringe gasket (70) wherein a peripheral side surface (8) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 2 attached to the end of this office action) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant (also labeled by the examiner on Figure 2).

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about

5mm. Furthermore, with respect to claims 6-8, there is no disclosure of the gasket's diameter, its height, its first diameter, or its second diameter

With respect to the specified gasket dimensions in the claims 1 and 6-8, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

7. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as applied to claim 1, and in view of Akaike et al. (U.S. 5,061,247).

Trull et al. sets forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the hardness of the gasket being between 55 to 60 (JIS hardness meter). Akaike et al. in column 5 lines 58-59 discloses that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as applied to claim 1, and in further view of Ito (U.S. 5,063,025).;

Trull et al. sets forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the material of the gasket being laminated polyethylene flouride. In any case, Ito in column 5 lines 1-7 discloses that a syringe gasket is commonly coated with a thermoplastic resin

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such as polyethylene or polypropylene (Teflon). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene or polypropylene, in order to achieve optimum gasket functionality and protection within a syringe device.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al as applied to claim 1, and in further view of Trull et al. as modified by Ito and Akaike et al. in claims 2 and 3.

Claims 4 and 5, the claims do not add any structural limitation on the claimed invention. Furthermore it was inherent, even trivial, in the art at the time the invention was made that any syringe device with a slideable plunger can be pre-filled with any liquid, including a contrast medium, and that the liquid can be tightly closed with the gasket by simply pre-applying pressure to the plunger.

### *Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited to further show the state of the art with respect to gaskets for syringes.

U.S. Pat. 5, 688, 252 to Matsuda et al.

U.S. Pat. 5, 397, 313 to Gross

U.S. Pat. 4, 303, 070 to Ichikawa et al.

The applicant is directed to pay close attention to tapered slants in the listed references.

***Contact Information***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (703) 305-0054. The examiner can normally be reached on M-F 8 A.M. - 6 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on (703) 308-0102. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

*ECS*  
Emmanuel Sayoc  
Patent Examiner  
Art Unit 3746

ECS  
December 17, 2002

*CHARLES G. FREAY*  
CHARLES G. FREAY  
PRIMARY EXAMINER